UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,185	06/24/2005	John Royle	0148/386US	8580

23638 7590 10/29/2008

ADAMS INTELLECTUAL PROPERTY LAW, P.A.
Suite 2350 Charlotte Plaza
201 South College Street
CHARLOTTE, NC 28244

EXAMINER	
PATEL, PRITESH ASHOK	
ART UNIT	**PAPER NUMBER**
4158	
MAIL DATE	**DELIVERY MODE**
10/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,185	ROYLE, JOHN	
	Examiner	Art Unit	
	PRITESH PATEL	4158	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 45-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 45-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

3. Claims 1, 2, and 64-66 are rejected under 35 U.S.C. 102 (b) as being anticipated by MacDonald et al. (US Patent 5776170).

Concerning Claims 1 and 2, MacDonald et al. discloses a pulse generating unit connectable to two electrodes able to provide a series of electrical pulses to a patient's body (Abstract). The pulse generating unit outputs positive and negative polarity pulses in series, each pulse width being around 10 microseconds and having a temporal spacing in between pulses (Column 3, Lines 60-67).

Concerning claims 64-66, MacDonald et al. discloses two electrodes connectable to a pulse generating unit that produces an analgesic effect by reducing pain via the central nervous system leaving the peripheral nervous system mildly affected or not at all (Abstract).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 45-63 are rejected under 35 U.S.C. 103 (a) as being unpatentable over MacDonald et al. (US Patent 5776170).

Concerning claim 45, MacDonald et al. discloses an impulse width of 10 microseconds (column 3 line 60). It would have been obvious to one of ordinary skill in the art at the time of the invention to pick a value of impulse width around the value of 10 microseconds and get the same therapeutic quality based upon MPEP 2131.03 : **"[A]nticipation under § 102 can be found only when the reference discloses exactly what is claimed and that where there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account."** ***Titanium Metals Corp. v. Banner*****, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims to titanium (Ti) alloy with 0.8% nickel (Ni) and 0.3% molybdenum (Mo) were not anticipated by, although they were held obvious over, a graph in a Russian article on Ti-Mo-Ni alloys in which the graph contained an actual data point corresponding to a Ti alloy containing 0.25% Mo**

and 0.75% Ni.).

Concerning claims 46-51, MacDonald et al. discloses a spacing of 4 microseconds or more between impulses (column 3, line 61). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify MacDonald to use 4 or 6 or 10 or 20 microseconds of spacing between impulses. It would have further been obvious to one of ordinary skill in the art at the time of invention that a temporal space is inherent between a plurality of contiguous impulses, a majority of impulses, and all impulses.

Concerning claims 52-54, MacDonald discloses a square wave in a circuit whose pulse width is set by a variable resistor (Column 4, lines 39-42). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the circuit of MacDonald et al. to produce an impulse with an asymmetric shape or a peak magnitude of 30% or 5% or 1% of the pulse width depending on desired exposure of voltage of an impulse to a patient. It would have further been obvious to have a peak magnitude that is 70% of the pulse width to increase desired exposure of voltage to patient. The manipulation of a circuit is obvious to one of ordinary skill in the art at the time of the invention.

Concerning claims 55-57, MacDonald et al. discloses an amplitude of 180V or more and an amplitude of 450V to 1kV (Claims 2 and 3 in MacDonald et. al.). It would have been obvious to one of ordinary skill at the time of the inventions to use voltage range from 150V to 250V or 50V to 450V for amplitude values for an electrode apparatus. It would further have been obvious to one of ordinary skill in the art at the

time of the inventions to use equal voltage values for the negative and positive amplitudes to reduce strain on the apparatus.

Concerning claim 58, MacDonald discloses the use of temporal spacing in between impulses and series of pulses as seen in column 3, line 61. It would have been obvious to one of ordinary skill in the art at the time of the invention that during the spacing between impulses the output of the pulse generating unit remains at a level substantially equal to 0V.

Concerning claims 59, MacDonald discloses the use of frequency greater than 100 Hz and that typically the frequency of 150kHz is also usable (Claim 5 of MacDonald et al. and column 4, line 19; respectively). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a range of 100 Hz to 250 kHz or 1 kHz to 250 kHz or 1 to 5 kHz or 2 kHz to 3 kHz as applied to the use of the apparatus disclosed.

Concerning claims 60-63, MacDonald et al. discloses a series of pulses consisting of impulses with a temporal spacing as discussed before (column 3, line 61). It would have been obvious to one of ordinary skill in the art at the time of the invention to understand that a series of pulses can have third impulse spaced from the second impulse by a temporal spacing, and that a series of impulses are a series of intermittent pulses. It would further have been obvious to one of ordinary skill in the art at the time of the invention to use a ratio of time period of no impulse to time period of impulse in the range of 1:3 to 1:20 to determine the length of time electrical impulses are delivered to the body and the time period of no pulse occurs at least once in a second as lasts for at

least 0.5 millisecond. The obviousness of using the parameters discussed lies the inherency of use of a series of pulses and an electrode apparatus.

7. Claims 67-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacDonald et al. in view of Effenhauser (US Patent 6032073).

Concerning Claims 67-70, MacDonald et al. discloses a method of using two electrodes connected to a pulse generating unit that provide a series of positive and negative impulses and a maximum voltage of 450V (abstract and column 3, lines 59). MacDonald et al. does not disclose the use of iontophoresis electrodes with a medication for delivery to the body. Effenhauser discloses the use of iontophoresis electrodes to deliver medication to the body for a therapeutic effect (Column 1, Lines 56-64).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify MacDonald et al. with iontophoresis electrodes as taught by Effenhauser. The power and variability in the pulse generating unit of MacDonald et al. could have enhanced the therapeutic effects of the device by providing simultaneous medication delivery. It would further have been obvious to utilize a 50 V amplitude during iontophoresis to reduce overdosing a patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PRITESH PATEL whose telephone number is (571)270-

7025. The examiner can normally be reached on Monday-Friday 7:30Am-5:00PM, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571)272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. P./
Examiner, Art Unit 4158
10/1/2008

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 4158